

# Exhibit 38

# **CONFIDENTIAL & PRIVILEGED**

**Advanced Cardiovascular Systems, Inc.**

## **INVENTION DISCLOSURE**

To: Legal Department

For Legal Department Use Only

cc: R & D Director

Docket No. 10040 CER  
Date Assigned June 1, 1994

### **Descriptive Title of the Invention**

The Proximal Shaft of a Dilatation Catheter, Fabricated from an Engineering Thermoplastic Polymer at Low Cost, which Provides Enhanced Push, Kink Resistance, Low Profile and Ease of Assembly to the Catheter.

### **Description and Use**

This invention is proximal shaft tubing of a dilatation catheter, particularly over the wire type, that is made from an engineering thermoplastic polymer that has an attractive combination of characteristics. These characteristics are:

- 1) easily extrudable so that the shaft can be produced at low cost,
- 2) high modulus of elasticity so that the shaft has relatively high stiffness to provide good "push" to the assembled catheter,
- 3) high strength so that relatively thin wall extrusions can be used which allow for low shaft profile,
- 4) relatively high elongation for this class of polymer so that assembly processes such as tube expansion and necking can be readily accomplished, and
- 5) good kink resistance so that at low profiles, the shaft doesn't kink during anticipated normal use.

We have found that material properties in the following ranges are particularly attractive: a) tensile strength  $\geq 10,000$ psi, b) tensile elongation  $\geq 50\%$ , and c) tensile modulus of elasticity  $\geq 300,000$ psi.

Several engineering thermoplastics have been evaluated and polyetheretherketone (PEEK) has been found to be most attractive. In particular, Victrex® PEEK grade 381G from Victrex corporation has been used in this development. This material extrudes easily into thin wall small tubing (.032" ID / .038" OD) and has tensile strength of  $\geq 14,000$ psi, a modulus of  $\geq 400,000$ psi., elongation of between 60% and 200% depending on extrusion conditions and good kink resistance at these tubing dimensions. Several prototype over the wire catheters have been assembled with this material as a proximal outer and inner shaft.

Other materials have been evaluated for this application. They include Elastinite, which provides excellent performance but at a high cost. Thermoset polyimide is another material which may provide similar performance to PEEK, however costs for this material is  $> \$1.50$ /ft (it cannot be extruded) compared to PEEK tubing costs of  $< \$0.20$ /ft. and the elongation is much less than 50%. Polyimide also cannot be necked or expanded adequately for catheter assembly. Several engineering thermoplastics have been evaluated including polyetherimide, polyphenylene sulfide, polysulphone, polyethersulphone and

"Dilatation Catheter with PEEK Proximal Shaft"

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polyaryletherketone. Of all materials evaluated, we found PEEK to have the best combination of characteristics for the proximal shaft application. The modulus of elasticity of polysulphone and polyethersulphone are less than that of PEEK. Polyetherimide and polyaryletherketone were more difficult to extrude into thin wall proximal shaft tubing than was PEEK. Polyphenylene sulfide tubing at the desired dimensions has unacceptable kink resistance.

### Projected Generic Scope

This invention has applicability to all dilatation catheters where improved "push" from stiffer proximal shaft components is desirable. The material of choice is PEEK, however any engineering thermoplastic polymers, including those mentioned above and polyetherketone (PEK), polyetherketoneketone (PEKK), polyarylketone, polyketone and others which have the combination of properties mentioned above would fall within the scope of this disclosure.

### References

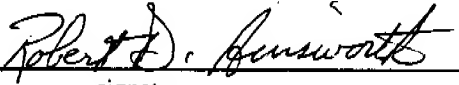

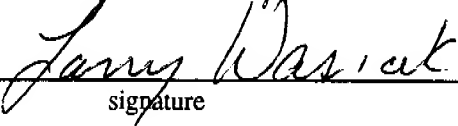
We are not aware of any publication or patent which describes the use of the engineering thermoplastic polymers mentioned above for proximal shafts of dilatation catheters for the purposes described. While nylon polymers may be considered engineering thermoplastic polymers, they generally do not possess the mechanical properties mentioned above.

There are two recent ACS invention disclosures that describe the use of PEEK in proximal shafts of dilatation catheters and this disclosure expands upon these. One was submitted by Tai Cheng, docket number ~~8980~~<sup>8980</sup>, and one submitted by Larry Wasicek in March of 1994, docket number ~~9260~~.

### Disclosure or Use

Over the wire catheters containing PEEK proximal shaft components have been evaluated for ACS in various animal studies and heart model studies by physicians. To our knowledge, no public disclosure or commercial use of this invention has been made.

### Submitters

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name	signature	date
Tai Cheng		5/31/94
name	signature	date
Larry Wasicek		5/27/94
name	signature	date

### Read and Understood the completed Invention Disclosure (not a submitter)

Daniel Cox		5/27/94
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